

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
 - FADED TEXT
 - ILLEGIBLE TEXT
 - SKEWED/SLANTED IMAGES
 - COLORED PHOTOS
 - BLACK OR VERY BLACK AND WHITE DARK PHOTOS
 - GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

UK Patent Application GB 2 218 831 A

(43) Date of A publication 22.11.1989

(21) Application No 8811591.0

(22) Date of filing 17.05.1988

(71) Applicant

Mark John Newland
95 Jewel Road, Strouden, Holdenhurst, Bournemouth,
BH21 0JW, United Kingdom

(72) Inventor

Mark John Newland

(74) Agent and/or Address for Service

Gill Jennings & Every
53-64 Chancery Lane, London, WC2A 1HN,
United Kingdom

(51) INT CL¹
G06F 15/42

(52) UK CL (Edition J).
G4A AUX
U1S S1030

(56) Documents cited

GB 2133166 A EP 0251520 A2 US 4731726 A
US 4575804 A US 4428050 A
Medical and Biological Engineering and Computing
(GB); Vol 24, No 6, Nov'86, pp-577-584.

(58) Field of search

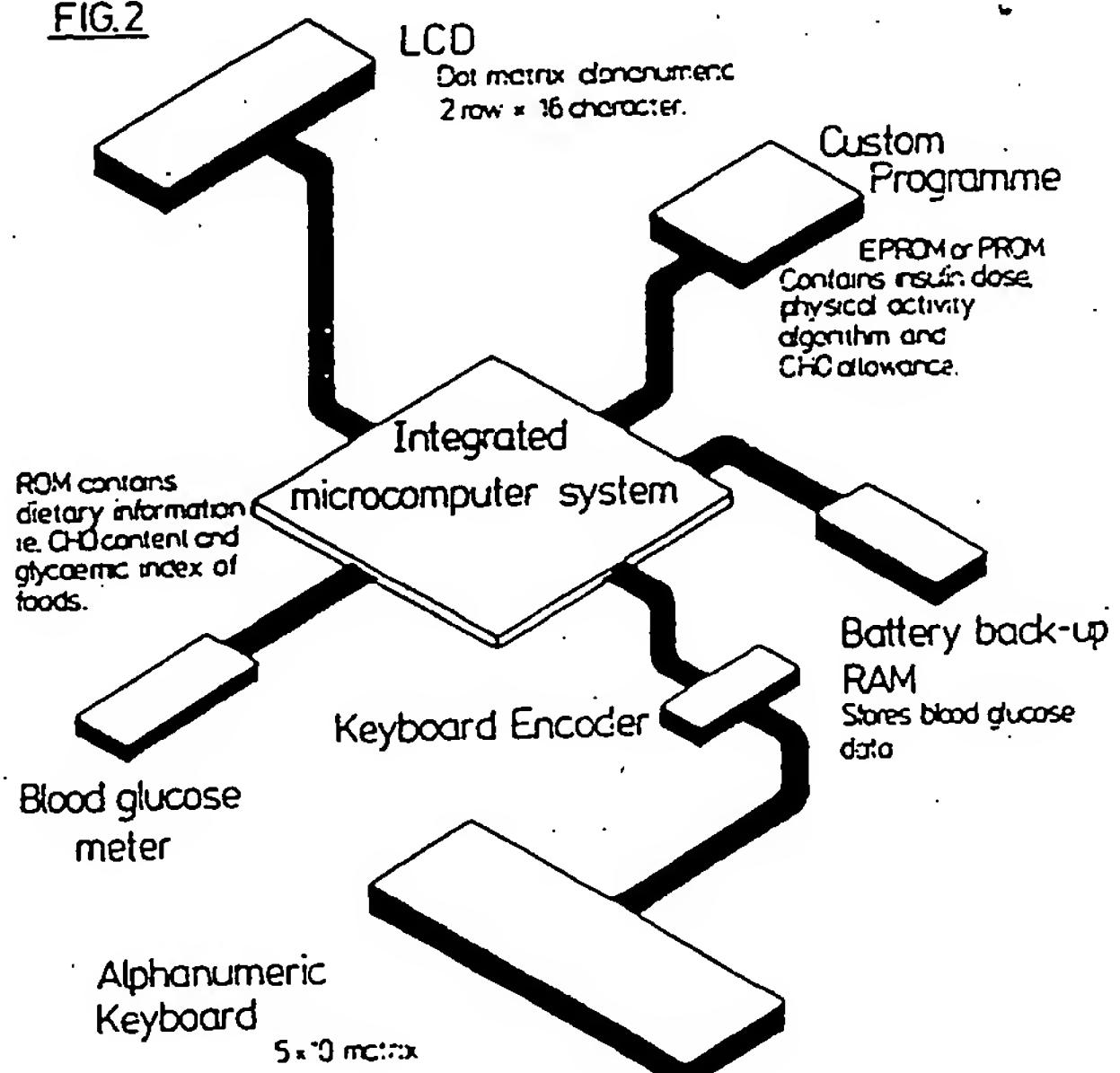
UK CL (Edition J) G4A ADT AUX
INT CL¹ G06F
On-line database INSPEC

(54) Personal medical apparatus

(57) A personal medication computer includes data entry means, such as a key pad, for entry of data relevant to a user's medical condition and a memory for storing data including pre-programmed prescribed dosage data of a medication for the user. An analysis system provides further data for use in combination with the data stored in memory. A stored programme is used to compute a medication dosage for the user from the stored data and from the data from the analysis system. The computed medication dosage, together with other user information, is shown on a display.

In a preferred example the analysis system comprises a blood glucose meter and the computer calculated insulin dosages for a diabetic user.

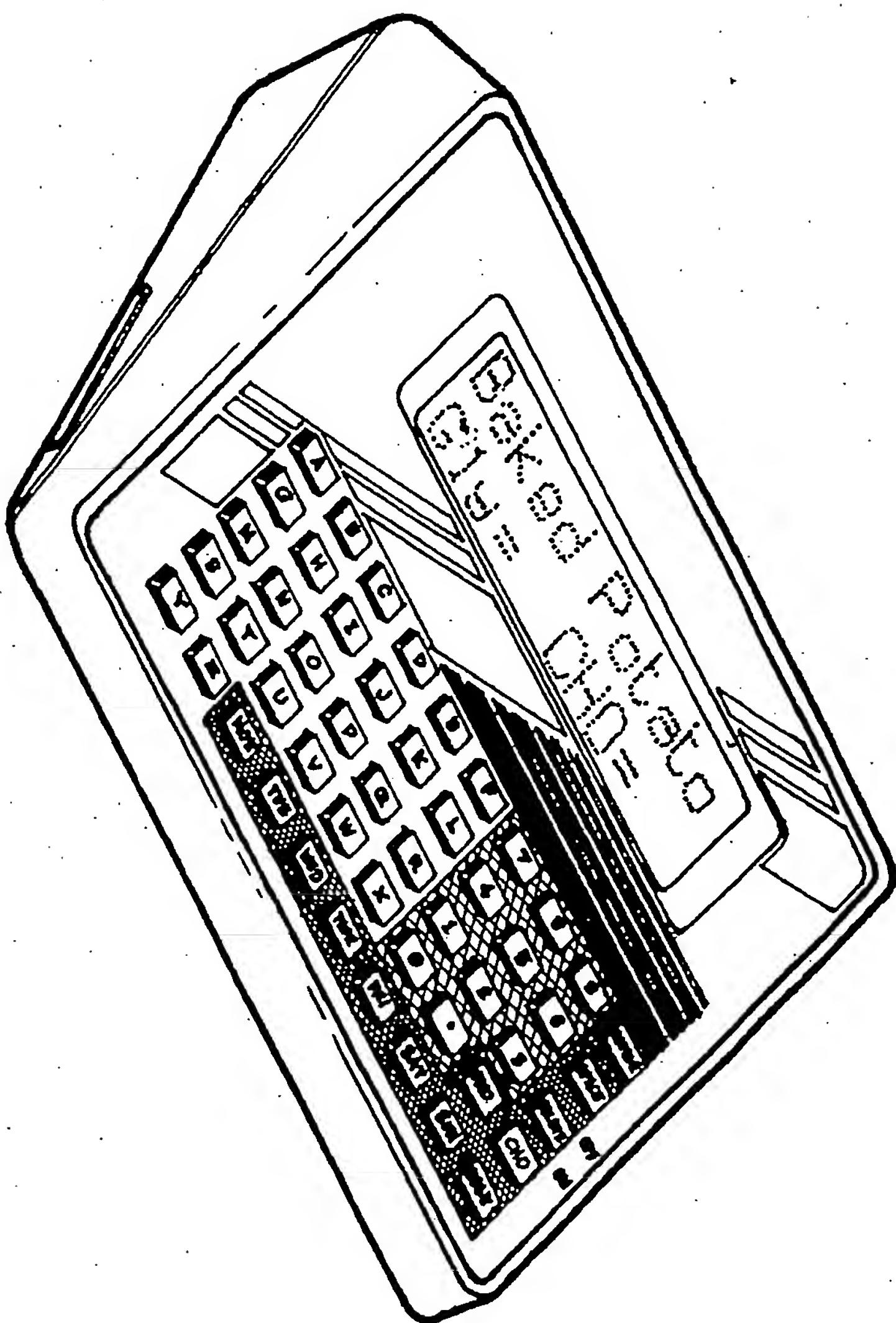
FIG.2



1/3

2218831

FIG.1



2218831

FIG.2

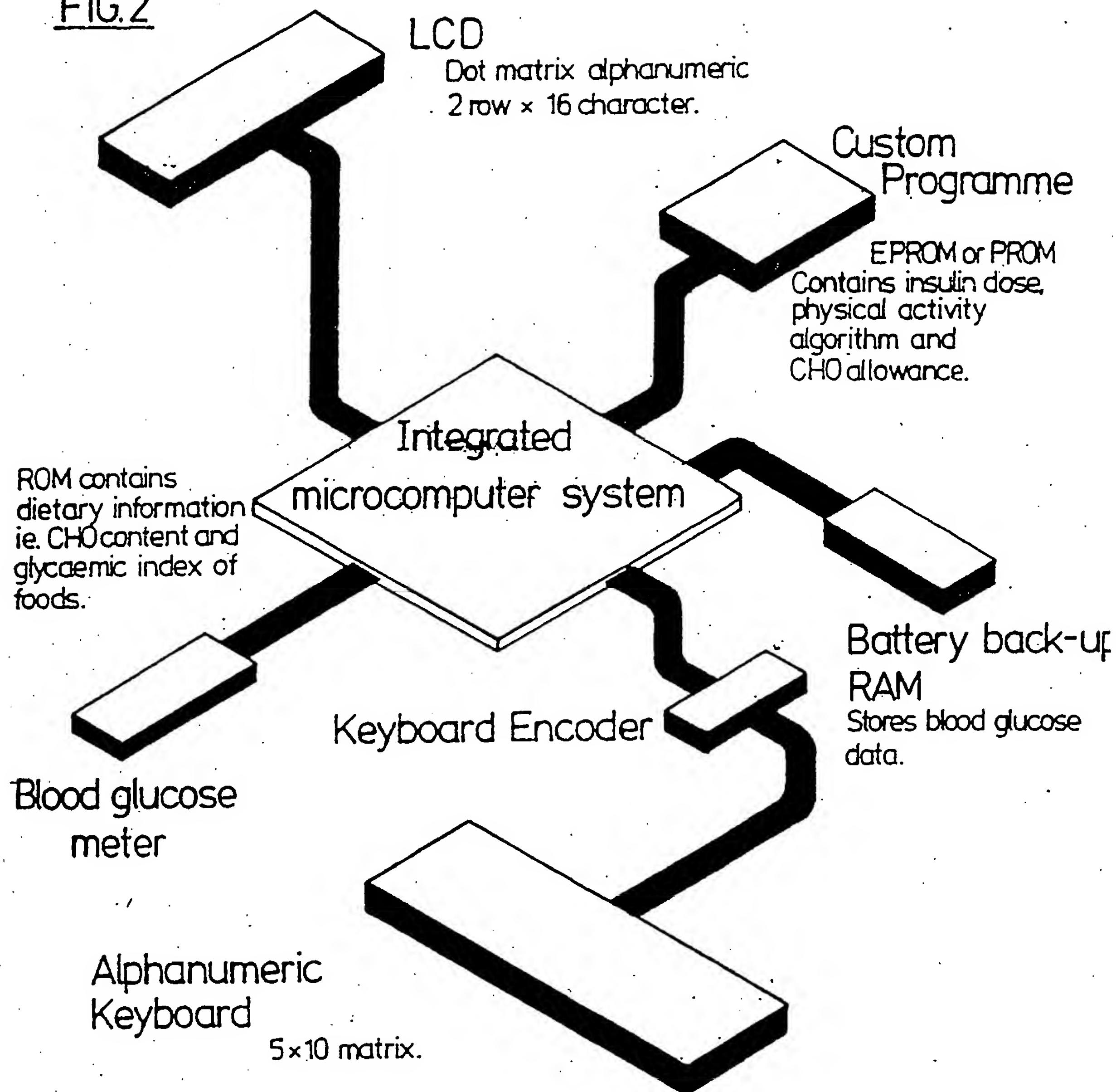
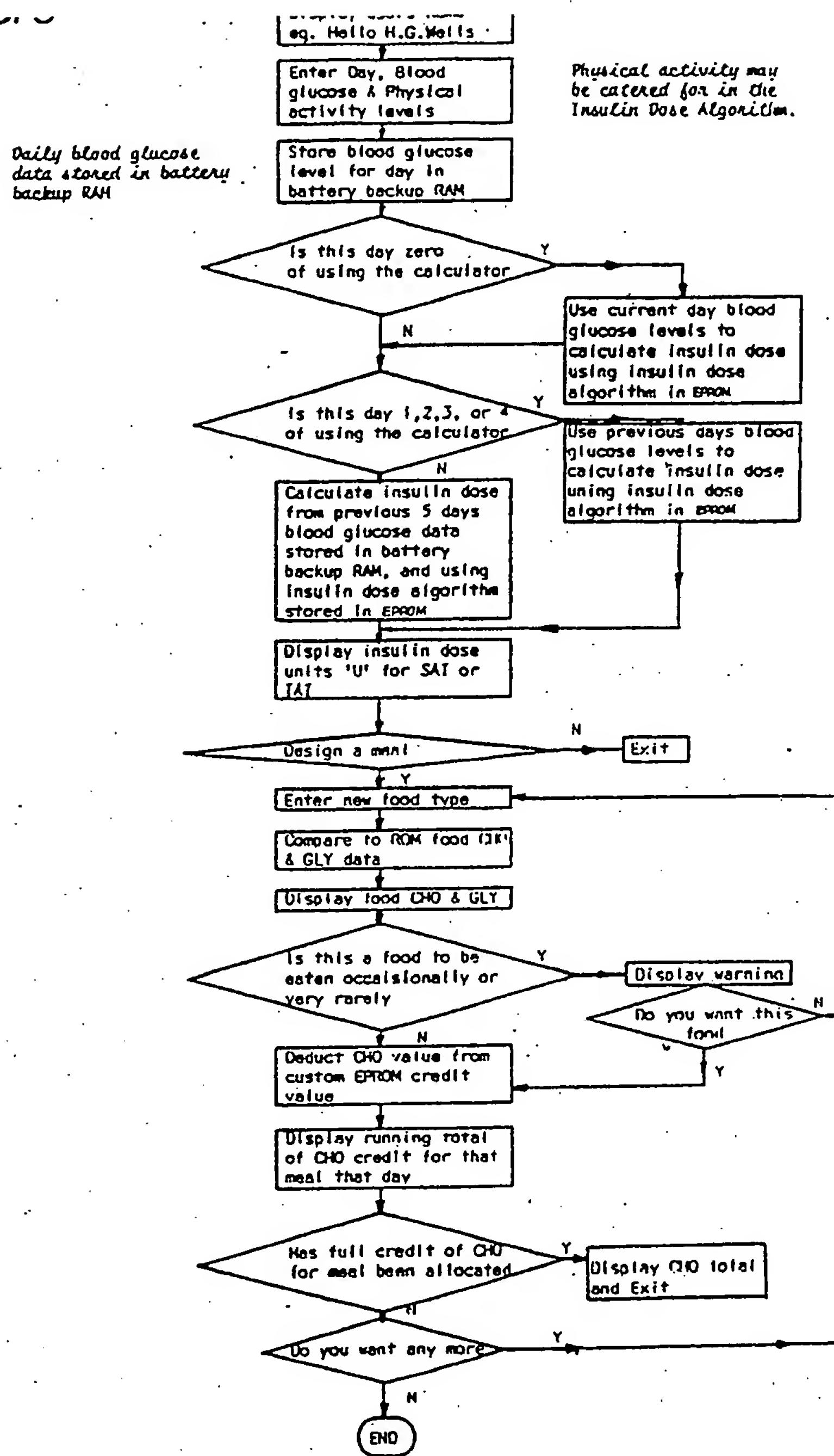


FIG. 3



Physical activity may be catered for in the Insulin Dose Algorithm.

2218831

Acronyms:

CHO - Carbohydrate
GLY - Glycemic Index
SAI - Short Acting Insulin
IAI - Intermediate Acting Insulin

RAM - Random Access Memory
ROM - Read Only Memory
EPROM - Electrically Programmable Read Only Memory

PERSONAL MEDICATION APPARATUS

2218831

This invention relates to the personal medical apparatus. Persons with medical conditions, particularly chronic medical conditions such as diabetes, are faced with the continual problem of organizing their activities and planning ahead so as to follow an individually prescribed course of medication and which may include their diet. At present, many persons with such chronic medical conditions have to rely on a combination of written material, such as diet and medication sheets, and their memory. This can be unreliable and unsatisfactory and leads to a less than optimum control of the medical condition.

According to the present invention there is provided a personal medication computer comprising:

a data entry means, such as a keyboard, for entry at certain times of data relevant to the person's individual medical condition at that time;

a memory storing data relevant to the medical condition including prescribed dosage data of a medication for the person;

a blood glucose meter for the analysis of blood tests which are used in computations and the data stored in a memory (applicable to medical conditions where by blood chemistry is required to be monitored);

a stored program operable to compute a medication dosage for the person on the basis of data entered on said keyboard and data stored in said memory; and

a display to display the computed medication dosage.

person to enter their dietary requirements and preferably also their current expected physical activity level. Daily blood glucose level data are preferably stored in memory for several days. The memory stores insulin dosage data and the stored program is operable to calculate an insulin dosage for the person on the basis of the entered blood glucose level and the stored insulin dosage data. The stored program preferably comprises an insulin dose algorithm involving blood glucose level data over several days and the person's physical activity level.

The stored program preferably also causes the display to display to the person their current individual carbohydrate (CHO) allowance, e.g. for that day.

The stored program is suitably embodied in a PROM and may be adapted and modified on medical advice as the person's diabetic condition alters over a period of time.

The computer may also be provided with a memory storing dietary data relevant to diabetes. The dietary memory may store the CHO content and the glycaemic index of a very large range of foods.

An embodiment of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a personal medication computer according to the invention;

Figure 2 is a schematic block diagram of the major components of the computer; and

Figure 3 is a flow chart describing operation of the computer of Figures 1 and 2.

Diabetes is defined as two types: (1) Insipidus; which is a disorder of the pituitary (a bean sized gland at the base of the brain, controls growth) causing excessive thirst and urination.

(2) Mellitus; a condition in which sugar and starch are not properly absorbed, with thirst, emaciation and excessive urine containing glucose and in extreme cases, acetone as well.

In simple terms, diabetes is a disorder in which the body is unable to control the amount of sugar in the blood, because the mechanism which converts sugar to energy is no longer functioning properly. This leads to an abnormally high level of sugar in the blood, which gives rise to a variety of symptoms initially and, if uncontrolled over several years, may damage tissues of the body. Therefore the treatment of diabetes is designed to reverse any symptoms and prevent any serious problems developing later. Diabetics are unable to produce sufficient quantities or in some cases any insulin. Insulin is produced by the beta cells of the islets of Langerhans within the pancreas (a gland about 150mm x 35mm located behind the lower portion of the stomach) and is responsible for assimilating blood glucose. In a normal person blood sugar rises after a meal and falls again when fasting. Usually, in the fasting state on rising in the morning, the amount of sugar in the blood is about 80mg/100ml, but seldom exceeds 160mg/100ml even after eating a heavy meal containing a lot of sugar. The diabetic usually has a blood sugar level above normal and can easily exceed 200mg/100ml. There is no precise state in which diabetes is present as non-diabetic's blood sugar levels occasionally rise above normal.

diabetics are faced with the problems of organising their lives and planning ahead and following a carefully structured diet, medication or both. The treatment depends on the type of diabetes diagnosed, which can range from mild to severe. The mild type is often called maturity onset, type two or non-insulin dependent diabetes. The type two cases occur in middle aged people frequently associated with obesity. These cases are easily treated by dietary control to reduce weight and regain normal health. Sometimes diet alone is not sufficient therefore tablets are prescribed which stimulate the pancreas to produce more insulin. Severe diabetes often termed type one or juvenile onset diabetes and can occur at any age, but is typified by that occurring in children and young adults. The onset of diabetes in these cases is generally more sudden and the symptoms more severe. Treatment is also more complex as it involves diet and insulin injections. Checks are performed by the patient in the form of urine and blood tests. These give a good indication of the control a patient has and how the diet and medication are working. It is the type one insulin dependent diabetes mellitus (IDDM) where the invention has its best defined niche.

The invention can be of greatest benefit to people with IDDM, and can give information on a prescribed treatment based on blood tests presently carried out by diabetics as a part of their daily routine treatment. Blood glucose meters are used for accurate readings on blood glucose tests. One of the many existing or newly developed blood glucose meters can be a part of the invention with the blood glucose data being fed directly to the microcomputer system. From this data is calculated the insulin dose to be injected and the quantity displayed to the user. The user is then offered an option to calculate dietary values of foods.

The invention is intended to give greater precision, control and simplify the process in which diabetics have to adhere to in order to control their condition and maintain good health. At present, diet sheets, a prescribed medication and diet are used in various combinations to treat diabetes depending on the type. This data has to be remembered or referred to.

The invention can hold all this information thus avoiding having to resort to memory. As each person's requirements are totally individual and subject to change due to time, accidents, stress, illness, life style etc. the invention contains a custom program which houses all personal data. The custom program can easily and quickly be updated. To every patient one thing will be common, that is the CHO values of foods, normally expressed in terms of "exchanges" where one exchange = a quantity of food containing 10g of CHO. This information is stored in a ROM.

The invention is used by first conducting the blood glucose test, this information is relayed to the microcomputer system which processes it and displays on the display the quantity of insulin to be injected. The user is then presented with an option to compile a meal or "design a meal". A CHO value is displayed taken from the custom program which is their CHO allowance. The CHO allowance is treated as a credit value to be consumed evenly over the day in the form of set meals and snacks. On entering a food value the food CHO value is taken from the allowance and a running total remaining is displayed. Foods entered that should not be eaten or eaten very occasionally prompts a warning to be displayed. It will be appreciated that use of the invention enables a diabetic person to maintain better control of their condition, they do not have to remember food values, they can easily determine their optimum diet and medication and they can easily determine the glycaemic index and CHO values of a very wide range of foods.

changing the batteries and updating the custom program. As the invention is designed for ease of portability, its size is small. Therefore some sacrifice is made to the ideal sized alphanumeric keyboard. Even so a miniature keyboard for this application is not required for high speed data input. A small amount of information has to be keyed in, akin to that of an ordinary pocket calculator.

The invention preferably looks neat, compact and conservatively stylish. Consideration must be made for appearance as the largest age group to use this device are children and young adults.

Just over 2% of the U.K. population (600,000) are diagnosed as being diabetic (of this approximately 30,000 are under the age of sixteen) with an estimated 600,000 undiagnosed. Nearly 30,000 diabetes cases are diagnosed in the U.K. each year. There are over 30 million diagnosed diabetics in the world with another 30 million undiagnosed. Over 30% of diabetics are insulin dependent and affects a population age spread of 10 years of age upwards. This in theory gives a maximum possible market potential of 200,000 in the U.K. and something in the order of 10 million world wide. An additional 10,000 insulin dependent diabetics are diagnosed in the U.K. alone each year. The invention can be adapted for other medical conditions or illnesses requiring dietary and or medication management and control. Just diet control would be another application.

Insulin dosage adjustments using computer algorithms: a comparative study was published in the Medical & Biological Engineering & Computing magazine, November 1986. Below are the algorithms that produced superior results in respect to the speed of improving diabetes control and the avoidance of undesirable hypoglycaemia. The algorithms were tested based on the following assumptions. The morning short-acting insulin (SAIB) had major action between breakfast and lunch.

Also, the morning intermediate-acting (not U-100), insulin (IAIB) had major action between lunch and dinner, and its effect was reflected in the blood glucose concentration before dinner. The evening short-acting insulin (SAID) had major action between dinner and bedtime, and its effect was reflected in the blood glucose level at bedtime. Finally, the evening intermediate-acting insulin (IAID) had major action overnight, and its effect was reflected in the blood glucose test results on arising the next morning.

Accordingly, the specific insulin dose adjusting algorithms implemented were as follows. All doses were in units (U) and the blood glucose concentrations were in dl^{-1} .

$$\text{IAID}_0 = \text{IAID}_{-1} + \sum_0^{-5} (\text{BGB} - 110)_i / \sum_0^{-5} S_1 i$$

1

$$= \text{IAID}_0 [9(\text{BGB}_0 < 50) + 10(\text{BGB}_0 \geq 50)]/10$$

Where IAID_0 represented the intermediate-acting insulin dose at dinner on day 0, the current day. The '=' sign should be read as 'is replaced by' and the inequalities assumed binary values of 1 (true) or 0 (false). IAID_{-1} represented the intermediate-acting insulin dose taken at dinner the previous day. BGB represented the breakfast blood glucose level in the summation, which was over the current and previous days with $i = 0$ to -5 . $S_1 i$ were sensitivity factors which weighted the summation. BGB_0 represented the prebreakfast plasma glucose level on day 0.

$$IAIB_0 = IAIB_{-1} + \sum_{-1}^{-5} (BGD - 110)i / \sum_{-1}^{-5} S_2 i$$

2

$$= IAIB_0 [9(BGD_0 < 50) + 10(BGD_0 \geq 50)]/10$$

where $IAIB_0$ represented the intermediate-acting insulin dose at breakfast on day 0 and $IAIB_{-1}$ that of the previous day. BGD was the predinner plasma glucose level and the summation was over the five previous days with $i = -1$ to -5 and $S_2 i$ were other sensitivity factors. BGD_0 was the predinner plasma glucose concentration of the current day.

$$SAIB_0 = SAIB_{-1} + \sum_{-1}^{-5} (BGL - BGB)_i / \sum_{-1}^{-5} S_3 i + (BGB - 110)_0 / S_4 i$$

3

$$= SAIB_0 [9(BGL_0 < 50) + 10(BGL_0 \geq 50)]/10$$

where $SAIB_0$ represented the short-acting insulin dose at breakfast on day 0 and $SAIB_{-1}$ the corresponding dose the previous day. BGL and BGB were, respectively, the prelunch and prebreakfast plasma glucose levels on the current and each previous day. $S_3 i$ and $S_4 i$ were sensitivity factors.

$$SAID_0 = SAID_{-1} + \sum_{-1}^{-5} (BGS - BGD)_i / \sum_{-1}^{-5} S_5 i + (BGD - 110)_0 / S_6 i$$

4

$$= SAID_0 [9(BGS_0 < 50) + 10(BGS_0 \geq 50)]/10$$

where $SAID_0$ was the short-acting insulin dose at dinner on day 0 and $SAID_{-1}$ the corresponding dose of the previous day. BGS and BGD were, respectively, the presnack and predinner plasma glucose levels of the current and each previous day. $S_5 i$ and $S_6 i$ were sensitivity factors.

CLAIMS

1. A personal medication computer comprising data entry means for entry of data relevant to a user's medical condition; a memory for storing data including pre-programmed prescribed dosage data of a medication for the person; an analysis system for the analysis of data for use in computations in combination with the data stored in memory; a stored program operable to compute a medication dosage for the person on the basis of data entered on said data entry means, data from said analysis system and data stored in said memory; and a display to display the computed medication dosage and user information.
2. A personal medication computer as claimed in claim 1, wherein the data entry means comprise a key pad.
3. A personal medication computer as claimed in claim 1 or claim 2, wherein the memory comprises a PROM for storing pre-programmed data relevant to the medical condition including prescribed dosage data of a medication for the user and a RAM for storing data entered via the data entry means.
4. A personal medication computer as claimed in claim 3, wherein the analysis system comprises a blood glucose meter connected to a data input of the computer to provide data for storage in memory and for use, in combination with the pre-programmed data, in calculation of a medication dosage.
5. A personal medication computer as claimed in claim 4, wherein the RAM has a battery back-up to enable non-volatile storage of data from the blood glucose meter and the stored programme is operable to calculate a medication dosage from a current meter reading and a

pre-determined number of previous meter readings stored in the RAM.

6. A personal medication computer substantially as described herein with reference to Figures 1-3 of the 5 accompanying drawings.

10

15

20

25

30

35